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510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

Device Identification

Proprietary Name:	Triathlon™ Posteriorly Stabilized (PS) Total Knee System
Common Name:	Posteriorly Stabilized Total Knee Replacement
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	OR(87) JWH Prosthesis, Knee Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/ Polymer

The Triathlon™ PS Total Knee system is comprised of a femoral component, tibial tray, and tibial insert that are intended to be used in total knee arthroplasty (if replacement of the articular surface of the patella is required, the Duracon® patellar components are compatible with the Triathlon™ components). The Triathlon™ PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. Specific indications and contraindications for the Triathlon™ PS Total Knee System are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid arthritis
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The Triathlon™ Posteriorly Stabilized Total Knee System consists of three primary components: Triathlon™ Posteriorly Stabilized (PS) Femoral Component, Triathlon™ Primary Cemented Tibial Baseplate, and Triathlon™ Posteriorly Stabilized (PS) Tibial Insert. Optional Triathlon™ Femoral Distal Fixation Pegs are also available. If replacement of the articular surface of the patella is required, the Duracon® patellar components are intended for use with the Triathlon™ Posteriorly Stabilized Femoral Components.

The Triathlon™ Total Knee Posteriorly Stabilized Femoral Component is fabricated from cast cobalt-chromium-molybdenum alloy, and is intended for cemented application to replace the articulating surface of the distal femur. This posteriorly stabilized femoral component is utilized when total knee replacement is indicated, and the posterior cruciate ligament is non-functioning or absent, resulting in joint instability.

The Triathlon™ Total Knee Posteriorly Stabilized Femoral Component is available in right and left configurations, and eight proportional sizes to accommodate differences in patient anatomy. The interior surface of the component (except the interior surface of the PS box) is grit-blasted to increase surface roughness - this is intended to promote interdigitation of the polymethylmethacrylate (PMMA) bone cement with the surface texture and the apposing bone. This femoral component features an intercondylar box that engages the mating tibial insert eminence at 45° to 60° (depending upon size of implant). The superior portion of the box is open. This open box design is intended to reduce contact on the tibial insert eminence, and in the case of intra-operative or post-operative femoral fracture, allow the surgeon to use a retrograde femoral nail to treat the fracture. There are threaded attachment features on the distal and posterior aspects of the femoral component. The threaded attachment feature on the distal aspect of the component is to allow the use of modular pegs.

The Triathlon™ Primary Cemented Tibial Tray is fabricated from cast cobalt chromium molybdenum alloy. The Triathlon™ Primary Cemented Tibial Tray is neutral in configuration, and is available in eight proportional sizes. The undersurface of the tibial tray and the keel is grit blasted for interdigitation with PMMA bone cement. The keel of the tibial tray is designed with normalizations for rotational stability and cement interdigitation. The superior aspect of the tibial tray has a rim that contains tabs that mate with the outer periphery of the tibial insert, along with the locking wire used on the tibial insert. This locking feature is designed to provide secure attachment of the tibial insert to the tray, and is designed to reduce micromotion of the tibial insert on the tray.

The Triathlon™ Posteriorly Stabilized (PS) Tibial Insert is neutral in configuration, and is available in eight proportional sizes and varying thicknesses (9mm, 11mm, 13mm, 16mm, 19mm, 22mm, and 25mm). The insert is fabricated from ultra high molecular weight polyethylene and cobalt-chromium alloy. The minimum thickness of the tibial insert on the bearing surface is 6mm. The tibial insert features a tibial eminence (or post) that provides anterior/posterior constraint in clinical situations where the posterior cruciate ligament is absent or non-functional. As previously noted, the tibial eminence contacts the cam of the femoral component at 45-60 degrees of flexion. There is a relief on the anterior aspect of the tibial insert to accommodate the patellar tendon and patellar fat pad.

The Triathlon™ PS Tibial Insert incorporates a locking wire feature on the anterior aspect of the insert. This locking wire is fabricated from cobalt-chromium alloy, and engages under tabs on the anterior rim of the Triathlon™ Primary Tibial Baseplate. This wire-tab locking mechanism secures the insert into the baseplate.

Triathlon™ Distal Femoral Fixation Pegs are made available separate from the Triathlon™ Posteriorly Stabilized Femoral Component. These distal femoral fixation pegs are an accessory to the Triathlon™ PS Femoral Component, and are optional for use. These pegs are designed to provide rotational stability, and to aid the surgeon in the placement

of the femoral component on the prepared distal femur. The Triathlon™ Distal Femoral Fixation Pegs are fabricated from wrought cobalt chromium alloy. The distal portion of the fixation peg is threaded to allow the peg to be assembled to the distal threaded hole in the Triathlon™ PS Femoral component. The proximal portion of the peg is recessed to allow the use of a wrench to assemble the peg into the femoral component.

Equivalent products include:

1. Duracon® Monolithic Stabilizer Femoral Component
2. Duracon® Cruciform Tibial Baseplate
3. Duracon® PS Lipped Tibial Insert
4. Scorpio® Posteriorly Stabilized (PS) Total Knee System
5. Series 7000 Standard Tibial Tray

Testing was presented to support a claim of substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. William J. Cymbaluk
Vice President
Quality Assurance/Regulatory Affairs/Clinical Research
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K031729
Trade/Device Name: Triathlon™ Posteriorly Stabilized (PS) Total Knee System
Regulation Numbers: 21 CFR 888.3560
Regulation Names: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: June 3, 2003
Received: June 4, 2003

Dear Mr. Cymbaluk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Triathlon™ Posteriorly Stabilized (PS) Total Knee System 510(k) Premarket Notification

510(k) Number (if known): K 031729

Device: Triathlon™ Posteriorly Stabilized (PS) Total Knee System

The Triathlon PS Total Knee system is comprised of femoral components, tibial trays, and tibial inserts that are intended to be used with the patellar components of the Duracon® system in primary and revision total knee arthroplasty. The Triathlon™ PS Total Knee System is intended to be used in situations where the posterior cruciate ligament is absent, or cannot be preserved. Specific indications and contraindications for the Triathlon PS Total Knee System are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid arthritis
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
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Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- ♦ Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

The Triathlon™ PS Femoral Component and the Triathlon™ Primary Cemented Tibial Baseplate are intended to be implanted using bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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